



QUALITY ENGINEER II

We Deserve the Best – And So Do You!

High Growth Company
Opportunity to Learn and Grow
Shape your Career
See the Importance of Your Work

Millstone Medical Outsourcing is looking for an energetic individual to join its Quality Department as a Quality Engineer II. Millstone is a fast growing, fast paced medical service provider for the top Orthopedic companies in the industry. Millstone's business focus is sterile and non-sterile packaging of medical devices.

Millstone also engages in other activities, such as mechanical inspection and assembly, which are designed to meet the outsourcing requirements of medical device manufacturers seeking to reduce costs while maintaining high levels of quality, accuracy, and timeliness. We are FDA and ISO registered and employ a detailed internal quality system to ensure ISO compliance.

RESPONSIBILITIES:

- Responsible for documenting and executing process validations on various types of manufacturing equipment. Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ)
- Provide technical engineering support to the operations group
- Work with clients to accurately write client specific validation and procedures
- Complete statistical analysis and provide metrics to internal & external customers as required
- Train production operators during process qualifications and guide others in the use of test equipment/tooling. Serve as trainer for less experienced engineers.
- Act as a technical resource for Program Managers and customers
- Work independently and comfortably act as an authority when technical issues arise
- Work with internal customers from various levels of the organization
- Assess a situation with mechanical devices and develop plans to address issues that arise
- Create manufacturing work instructions and review and correct existing procedures/prints for accuracy
- Coordinate workload within the Engineering department
- Assist with department scheduling and priority setting. Take on additional responsibilities during start-up phase to assist Program Management.
- Identify and lead preventive action projects that reduce non-conformances and improve operational efficiencies
- Act as department lead in the absence of department management
- Consistently above average when it comes to productivity/efficiencies, sets the pace for others

- All other duties as assigned

KNOWLEDGE & SKILLS:

- Bachelor's Degree with at least 5 years of Quality Engineering experience, preferably in an ISO 13485 and FDA environment
- Excellent verbal and written English communication skills
- High attention to detail and the ability to work in a team environment are essential
- Ability to multitask and complete work independently is crucial
- Superior problem solving and decision-making skills
- Advanced mechanical aptitude with the ability to install, set up, & operate production equipment
- Experienced with establishing operating parameters for production equipment
- Working knowledge of AutoCAD and Mini-Tab
- Adept in use of calipers, micrometers, and other test equipment
- Highly proficient Technical writing skills for validations/procedures
- Advanced Math skills in algebra, trigonometry, & basic statistics concepts
- Understand statistical tools and use those tools to prove or disprove a theory
- Advanced ability to create spreadsheets and other documents
- Working knowledge of Good Manufacturing Practices (GMP's) with the ability to guide others to maintain GMP compliance
- Excellent interpersonal and customer service skills
- ASQ CQE certification highly preferred
- Six Sigma training a plus

PHYSICAL REQUIREMENTS:

Standing, stooping, light lifting (25 lbs. or less), manual dexterity, ability to read fine print, 20/20 vision or corrected 20/20 vision

ADDITIONAL INFORMATION:

Millstone Medical Outsourcing offers a competitive salary, health, dental and vision benefits beginning on the first day of employment and 401K with company match. Other benefits include paid vacation, paid sick time, holiday pay and voluntary benefits in addition to an employee-centric work environment. To learn more about Millstone Medical Outsourcing's opportunities, visit us online at www.millstonemedical.com. If interested in this position, please send your resume to hr@millstonemedical.com.

Millstone Medical Outsourcing provides equal employment opportunity to all applicants and employees. No person is to be discriminated against in any aspect of the employment relationship due to race, religion, color, sex, age, national origin, ancestry, disability, sexual orientation, gender identity, genetic information, citizenship status, marital status, pregnancy, veteran status or any other status protected by applicable federal, state, or local law.

All employment offers are contingent upon successful completion of our pre-employment drug screening and background/criminal check, consistent with applicable laws.